FOR PATENT GROUP USE ONLY:

INVENTION DISCLOSURE

DOCKET NUMBER:_
DATE RECEIVED:___
RECEIVED BY:___E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "*Guidelines for Drafting Invention Disclosures*."

1. TITLE OF INVENTION: Lead for left heart pacing through the coronary sinus

2. **PROBLEM TO BE SOLVED:** Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricule. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult the achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. **DESCRIPTION OF THE INVENTION:** Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): ___3___ pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.

Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig) . Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aide in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slighty withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transfered to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transfered to the end of the lead.

4. List advantages and novel features below:

a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.

b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.

c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.

d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.

e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.

f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target sight for placement.

g) If the design is implemented <u>without</u> a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.

h) The lead incorporates staight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

5. **List all present or future products this invention will be or could be incorporated into:**

6. **Clinical or pre-clinical evaluation:**

7. **The invention is described on page starting at 24 of Notebook No.: 1630.**

Succ ssful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. **Is the invention currently under development, in research, or are tests being scheduled:**
All of the above

10. **Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter?** ***NO***

If "YES", complete the following, as appropriate:

a. Title and date of publication _____

b. Date of first sale _____

c. Date of first public use _____

11. **Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?**
YES

If "YES", complete the following, as appropriate:

a. **Has the manuscript been accepted for publication at the time of the disclosure?** NO

b. **Type of document and title** U.S. Patent 5,411,546 and U.S. Patent 5,387,233.

c. **Document submitted to** _____

d. **Anticipated publication or presentation date** _____

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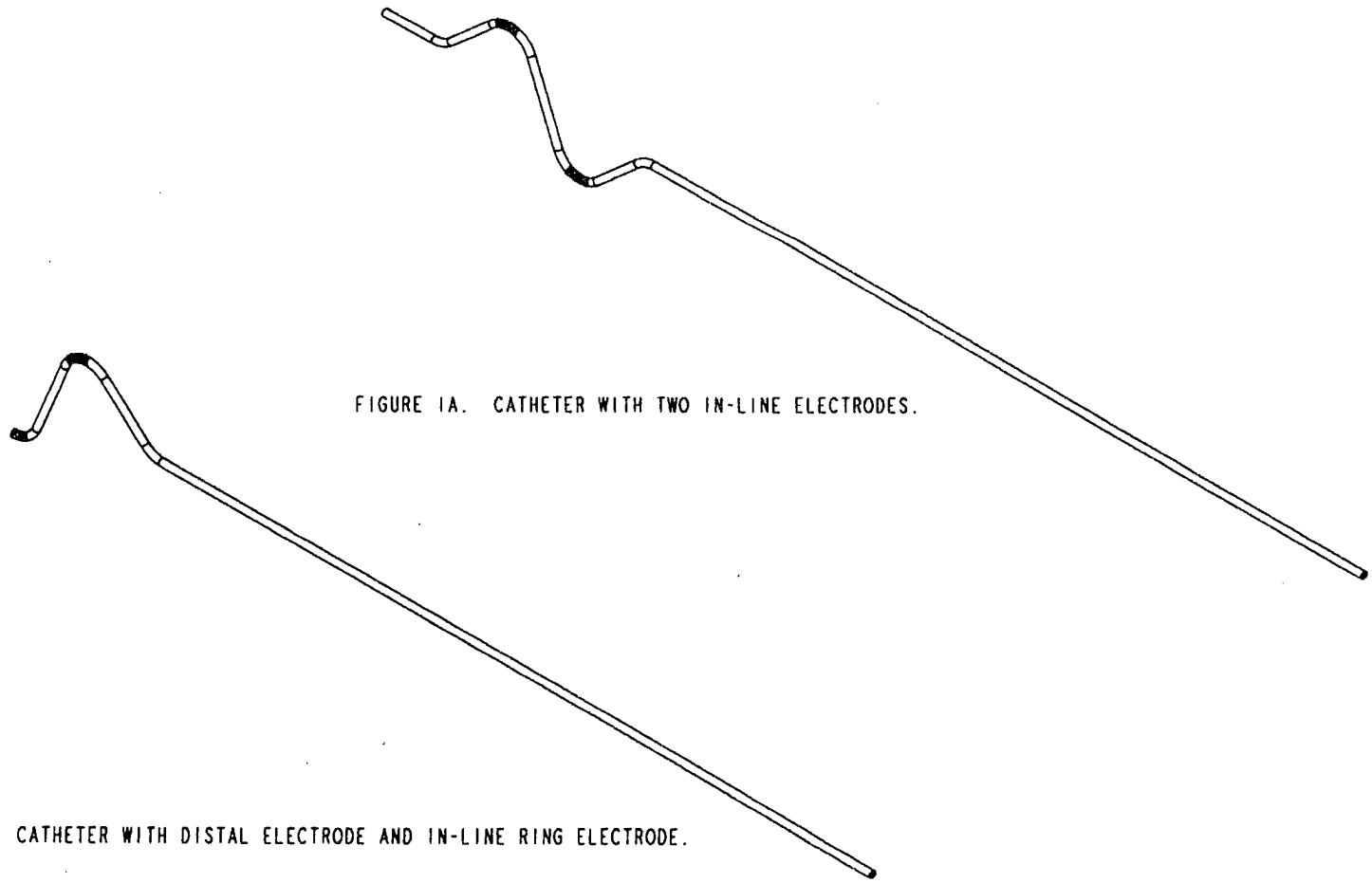

FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

FIGURE 1B. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE: 02/18/97

FILE NAME: zig_reg_polenil.drw

DRAWN BY: ABBE PIANCA DATE:

UNLESS OTHERWISE SPECIFIED ALL DIMS ARE IN INCHES ALL DIMS APPLY AFTER FINISH

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.XXX +/- .005
.XXXX +/- .0025
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SURFACE FINISH PER ANSI-B46-1

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TITLE
INTRAVENOUS CARDIAC LEAD

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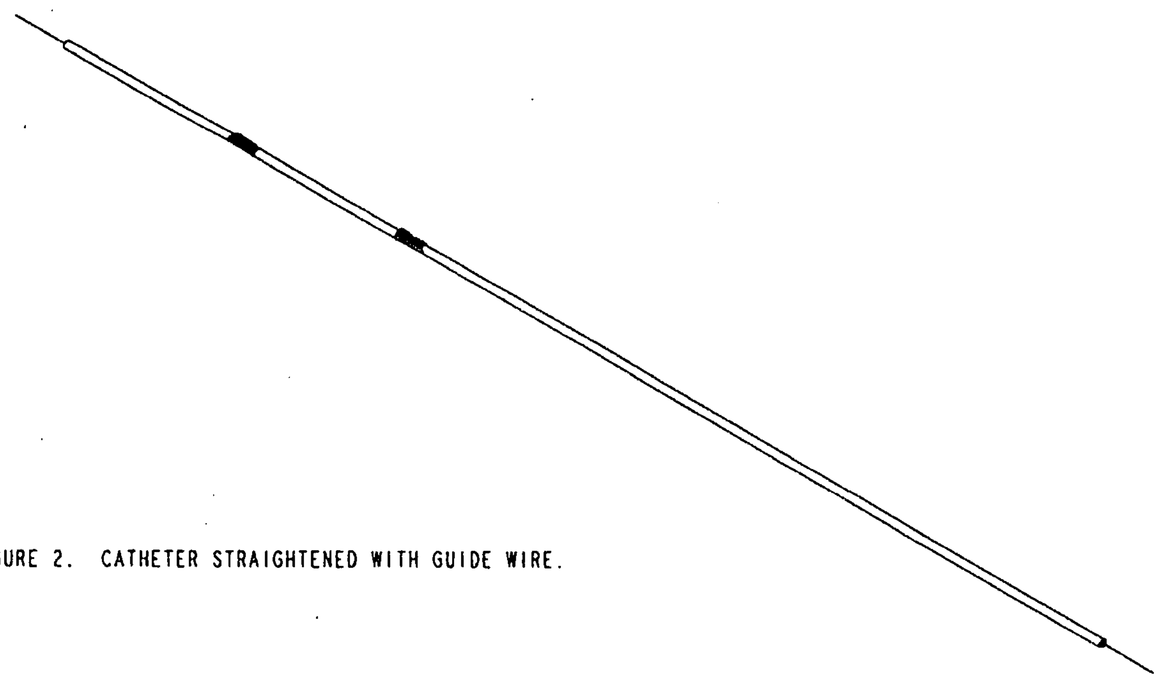

FIGURE 2. CATHETER STRAIGHTENED WITH GUIDE WIRE.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE: 02/21/97

FILE NAME: u/es2/apianca/pro/zig.zag.pofeall.drw

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DRAWN BY: ANNE PIANCA

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TITLE: INTRAVENOUS CARDIAC LEAD

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SIZE C | SCALE 1X | SHEET 2 of 3

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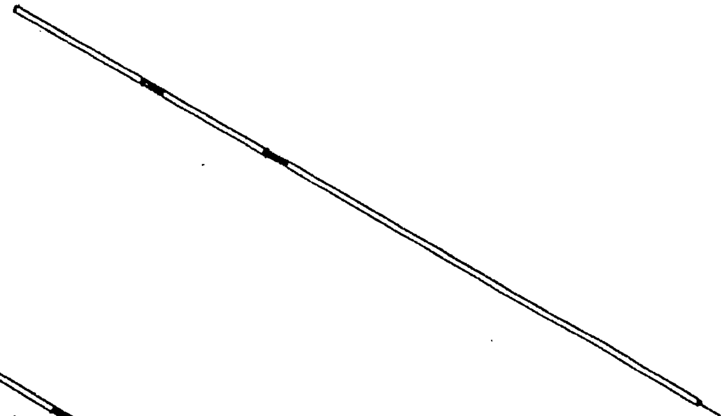

FIGURE 3A. CATHETER STRAIGHTENED WITH STYLET.

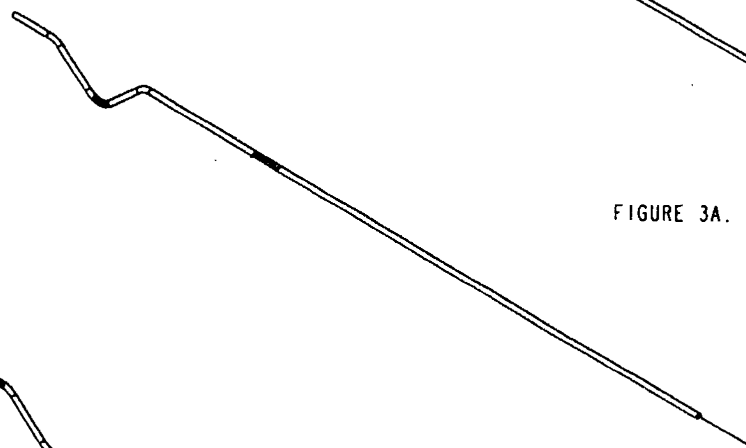

FIGURE 3B. CATHETER CANTED BY REMOVING STYLET WHICH PROVIDES STEERABILITY.

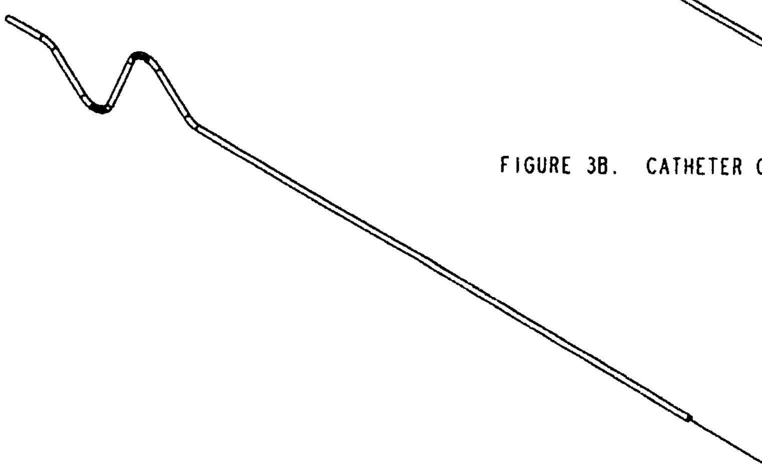

FIGURE 3C. STYLET REMOVED FURTHER THAN SHOWN IN FIGURE 3B.
THE CATHETER IS FURTHER CANTED WHICH AUGMENTS BENDING FOR STEERABILITY.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE: 02/24/97

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DRAWN BY: ARNE PIANCA DATE:

UNLESS OTHERWISE SPECIFIED ALL DIMS ARE IN INCHES ALL DIMS APPLY AFTER FINISH

TOLERANCES DECIMAL .XX +/- .01 .XXX +/- .005 .XXXX +/- .0005 ANGLES +/- 1 DEG FRACTIONS +/- 1/32

DO NOT SCALE DRAWING

SURFACE FINISH PER MS1-040-1

FILLET RADII ___ MAX BREAK ALL EDGES ___ MAX

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TITLE INTRAVENOUS CARDIAC LEAD

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SCALE 1X SHEET 3 OF 3

910251 REV E

Pacesetter, Inc.

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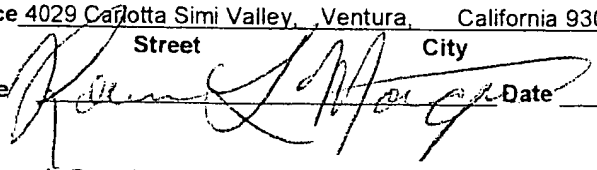
Signature  **Date** , **Supervisor** Gene Bornzin

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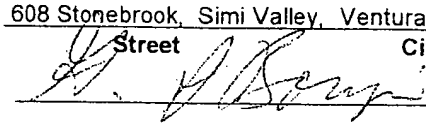
Signature  **Date** **Supervisor** Jason Sholder

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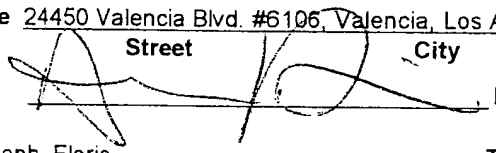
Signature  **Date** **Supervisor** Buehl Truex

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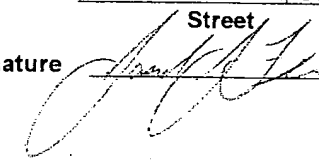
Signature  **Date** **Supervisor** Jason Sholder

WITNESSES: I have **read** and **understood** the attached invention, and/or the invention has been explained to me.

Signatur of Witness _____ **Date** _____

Signatur of Witness _____ **Date** _____